

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 512100-2058											
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on _____ Signature _____ Typed or printed name _____	Application Number 10/596,200	Filed 06-02-2006											
	First Named Inventor Kerdar et al.												
	Art Unit 1619	Examiner LEA, Christopher Raymond											
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <table style="width: 100%;"><tr><td style="width: 50%; vertical-align: top;"><input type="checkbox"/> applicant/inventor.</td><td style="width: 50%; vertical-align: top;">/Howard C. Lee/</td></tr><tr><td style="vertical-align: top;"><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</td><td style="vertical-align: top;">Signature Howard C. Lee</td></tr><tr><td style="vertical-align: top;"><input type="checkbox"/> attorney or agent of record. Registration number _____</td><td style="vertical-align: top;">Typed or printed name 202-292-1539</td></tr><tr><td style="vertical-align: top;"><input checked="" type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 <u>48,104</u></td><td style="vertical-align: top;">Telephone number 29 September 2009</td></tr><tr><td></td><td style="vertical-align: top;">Date</td></tr></table>				<input type="checkbox"/> applicant/inventor.	/Howard C. Lee/	<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)	Signature Howard C. Lee	<input type="checkbox"/> attorney or agent of record. Registration number _____	Typed or printed name 202-292-1539	<input checked="" type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 <u>48,104</u>	Telephone number 29 September 2009		Date
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	Date												
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.													
<input type="checkbox"/> *Total of _____ forms are submitted.													

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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REASONS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW

I. Status of claims

Claims 1-14 are pending in this application. An amendment after final was filed, but was erroneously not entered. The basis for the error is that the amendment to claim 14 did not raise new issues or require a new search, but was merely added to address the Examiner's 35 U.S.C. 112, second paragraph rejection which would have reduced the number of rejections for consideration in any Appeal Brief (The presence of the second "is" would merely constitute an objection to the claims and can easily be corrected via an Examiner's Amendment).

II. Basis for clear error in 35 U.S.C. 103(a) rejection

The Advisory Action contained several comments which indicated that the applicants' response to the final rejection was not properly considered. The basis for these errors is as follows:

A. Error is assertion of inseparability of properties for a compound/composition

The Advisory Action stated that "a chemical *composition* and its properties are inseparable." However, this premise is incorrect.

It is well known that a chemical *compound* and its properties are inseparable. *In re Papesch*, 50 C.C.P.A. 1084, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963). This premise can be extended to chemical compositions only if the components of the chemical composition of the applicants' invention and the components of the chemical composition of the prior art are identical. *see In re Spada*, 911 F.2d 705, 709 ("Products of identical chemical composition can not have mutually exclusive properties").

However, this is not the case here.

Whereas the applicants' claimed invention is specific for a particular active ingredient (lidocaine) and properties associated with the dosage form because of the use of lidocaine specifically as the active agent, a certain amount of lidocaine and the ratio of polymer to crosslinker, the combination of Rupprecht and Levin makes not such assertion or gives any direction to the simultaneous presence of these elements which are required to produce the claimed dosage form.

Given the many possibilities for active agents represented by Rupprecht and Levin, it cannot even be held that the combination of references would even direct one of ordinary skill in the art to the use of lidocaine.

In fact, Levin actively discourages those of ordinary skill in the art in using lidocaine for intranasal administration (see col. 4, lines 64 – 67 – “Clinically, intranasal administration of lidocaine has proven to be disappointing and is not widely used, not is it included in recognized cluster headache protocols.”)

Moreover, Levin’ invention when considered as a whole is directed toward the use of *long-acting* anesthetics which is a required element of their invention. Levin self-defines lidocaine to be a *short-acting* anesthetic and is optional aspect of their invention.

Therefore, one of ordinary skill in the are would not view the applicants’ claimed dosage form or method of use thereof to be identical to the dosage forms of Rupprecht and Levin nor would they be obvious variants thereof given lack of direction to the elements of the applicants’ invention (including the selection of lidocaine) and the teaching away for the use of lidocaine.

B. Error in applying the guidance of MPEP 716.01(c), section II and applying the proper evidentiary standard for establishing obviousness

The Advisory Action stated that “[t]he arguments of counsel cannot take the place of evidence in record.”, citing MPEP 716.01(c), section II. However, this section of the MPEP is referring to the nature and content of affidavits and declarations and consideration thereof. In this regard the applicants agree that attorney arguments cannot take the place of evidence of secondary considerations. However, this is not the argument which was made here.

As noted in MPEP 2145, “[i]f a *prima facie* case of obviousness is established, the burden shifts to the applicant to come forward with arguments and/or evidence to rebut the *prima facie* case. See, e.g., *In re Dillon*, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990). Rebuttal evidence and arguments can be presented in the specification, *In re Soni*, 54 F.3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995), by counsel, *In re Chu*, 66 F.3d 292, 299, 36 USPQ2d 1089, 1094-95 (Fed. Cir. 1995)... Office personnel should consider all rebuttal arguments and evidence presented by applicants. See, e.g., *Soni*, 54 F.3d at 750, 34 USPQ2d at 1687 (error not to consider evidence presented in the specification)”

The Examiner has an obligation to consider all of the evidence and arguments of record at the time of the Office Action and determine whether a *prima facie* case of obviousness exists. The applicants hold that when one of ordinary skill in the art considers the entirety of the record including the rebuttals to the positions taken by the Examiner, that skill artisan would not find that the preponderance of evidence (“more likely than not”) standard for establishing obviousness has been reestablished. The preponderance of evidence standards allows for some doubts with regard to exist to obviousness of the claims and there is no basis for the apparent holding by the Examiner that little to no doubt can exist with regard to obviousness in order for the claims to be deemed unobvious.